



May 17, 2005

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Ortho Molecular Products Inc.
3017 Business Park Drive
P.O. Box 1060
Stevens Point, WI 54481
715.342.9881 Phone
800.332.2351
715.342.9866 Fax
orthomolecularproducts.com

Office of Special Nutritional (HFS-450)
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

MAY 25 2005

Dear Sir/Madam:

This letter will serve as notification, pursuant to section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 101.93, that Ortho Molecular Products, Inc. is using the following claim on its label (see attached labels on page 2).

Name of Manufacturer: Ortho Molecular Products, Inc.
3017 Business Park Drive
P.O. Box 1060
Stevens Point, WI 54481

Statement Text: Gastrointestinal Support

Dietary Ingredients: Vitamin A (as Palmitate), Vitamin C (as Ascorbic Acid USP), Niacin USP, Vitamin B12 (as Methylcobalamin), Biotin, Choline Bitartrate, L-Methionine USP, Beet Leaf, Inositol, Milk Thistle Seed Extract (Standardized to contain 80% Silymarin), N-Acetyl Cysteine, Barberry Root Bark, Ox Bile Extract NF (Bovine), Radish Root, Artichoke Leaf Extract (Standardized to contain 5% Cynarin), Natural gelatin capsules, Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose, Silicon Dioxide.

Dietary Supplement Name: Ortho Liver Forte

As required, enclosed are two photocopies of this notification.

I certify that the information presented and contained in this notice is complete and accurate, and that Ortho Molecular Products, Inc. has substantiation that the statement is truthful and not misleading.

Sincerely,

Melissa Slager
Document Control / Training Manager
Ortho Molecular Products

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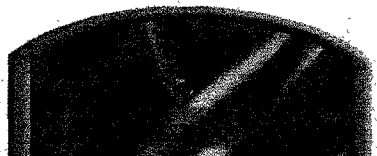
Attachment of Ortho Liver Forte Labels

Suggested Use: As a dietary supplement, 1-2 capsules three times per day or as recommended by your health care professional. Formulated to be free of allergens derived from: Gluten, corn, egg, dairy, peanuts, yeast, artificial colors and flavors. This product contains the following potential allergen: Asteraceae Family. Do not consume this product if you are pregnant or nursing. Consult your physician for further

information. As with all dietary supplements, some individuals may not tolerate or may be allergic to the ingredients used. Please read the ingredient panel carefully prior to ingestion. Cease taking this product and consult your physician if you have negative reactions upon ingestion. KEEP CONTAINER TIGHTLY CLOSED. STORE AT ROOM TEMPERATURE. KEEP OUT OF REACH OF CHILDREN. This product was sealed for your protection. Do not use if outer topged neck seal or inner seal are missing or damaged. Mfg. by Ortho Molecular Products, Inc., 3017 Business Park Drive, Stevens Point, WI 54481. Label ID L-OMP100-914060-8



Ortho Liver Forte



Dietary Supplement Product #914

60 Capsules

Supplement Facts

Amount Per % Daily		Serving Value	
Serving Size: 3 Capsules		Servings Per Container: 20	
3 capsules contain			
Vitamin A (as Palmitate)	6,000 IU	120%	
Vitamin C (as Ascorbic Acid USP)	25 mg	42%	
Niacin USP	40 mg	200%	
Vitamin B12 (as Methylcobalamin)	45 mcg	750%	
Biotin	180 mcg	60%	
Choline Bitartrate	540 mg	*	
L-Methionine USP	270 mg	*	
Beet Leaf	195 mg	*	
Inositol	180 mg	*	
Milk Thistle Seed Extract	180 mg	*	
(Standardized to contain 80% Silymarin)			
N-Acetyl Cysteine	135 mg	*	
Barberry Root Bark	135 mg	*	
Ox Ble Extract NF (Bovine)	75 mg	*	
Radish Root	60 mg	*	
Artichoke Leaf Extract	50 mg	*	
(Standardized to contain 5% Cynarin)			
* % Daily Value not established			

Other Ingredients: Natural gelatin capsules. This product may contain one or more of the following: Ascorbyl Palmitate, Magnesium Stearate, Microcrystalline Cellulose and Silicon Dioxide.
 † These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

OrthoMolecularProducts.com

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5/17/2005

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